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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 265,606	03 10 1999	RAINER ZIMMERMANN	LUD5330.3DIV	4727

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01 29 2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/265,606

Applicant(s)

ZIMMERMANN ET AL.

Examiner

Marjorie Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

In view of the new grounds of rejection set forth below, the finality of the office action mailed 3/26/01 is hereby withdrawn, and an action on the merits of pending claims 5 and 16-19 follows. All rejections and objections not repeated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

The claims recite an isolated protein consisting of the FAP α catalytic domain and at least one portion of a non- FAP α protein. Claim 17 specifically limits the non- FAP α protein portion to the extracellular domain of a CD8 protein. The specification discloses on page 22 that chimeric and fusion proteins which contain the catalytic domain of FAP α and non FAP α components are considered part of applicant's invention. The specification also discloses on page 21 that a fusion (chimeric) protein comprising the extracellular domains of FAP α and murine CD8 has FAP α catalytic activity. The specification does not specifically identify or teach (e.g. by starting and ending residues

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or by identification as a separate sequence) which "sections" of the entire FAP α protein are the catalytic domain and/or extracellular domain. As the specification teaches that a fusion protein comprising the extracellular domain of FAP α has catalytic activity, it is unclear if the entire extracellular domain is to be considered the "catalytic domain", or if a smaller portion of the extracellular domain is the "catalytic domain."

With regard to the extracellular domain, the specification teaches on page 12 that the extracellular domain comprises 5 potential glycosylation sites and teaches that Figure 1 indicates a putative transmembrane domain and potential glycosylation sites. However, originally filed Figure 1 does not actually indicate a putative transmembrane domain. Figure 1 does indicate putative glycosylation sites, but does not otherwise indicate any "boundaries" for an extracellular domain. The specification does not teach anywhere, by residue number or sequence, which portion of FAP α is specifically defined to be the extracellular domain. As neither the instant specification or drawings indicate the limits of either the putative transmembrane domain or the extracellular domain, the originally filed disclosure fails to fully and completely describe an extracellular domain of FAP α , therefore the specification also fails to provide a full and complete written description for a protein comprising the extracellular domains of FAP α and CD8.

With regard to a catalytic domain presumed to be different, or smaller, than the entire extracellular domain, Applicant argues in the response filed 7/17/01 that the catalytic domain of FAP α is specifically defined on page 13, Table 2 of the specification. Applicant also argued in a response filed 7/10/00 that amino acids 621-737 "are

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required, to constitute a catalytic domain" and state that the "specification is clear on this point." As set forth above, it is NOT clear which portion of the extracellular domain is required "to constitute" a catalytic domain. Applicant, in fact, contradicts himself with his argument in the response of 7/17/01, when he argues that "the structure required for catalytic activity" is "Gly-Trp-Ser-Tyr-Gly." The specification does not actually teach that ANY sequences are required for catalytic activity, but merely teaches that the extracellular domain of FAP α , comprises three segments "corresponding to" highly conserved catalytic domains found in serine proteases. It is known in the art that the motif "Gly-Trp-Ser-Tyr-Gly" is required for catalytic activity in some enzymes similar to FAP α , and FAP α clearly comprises this sequence, as shown in Table 2 of the instant specification. What other residues are "required" to constitute the catalytic domain in FAP α , however, is not clear, and is not defined by the specification. Applicant argues in the response filed 7/10/00 that amino acids 621-737 are "required", but the instant specification itself does not teach this, nor does the specification teach whether the catalytic domain consists of only amino acids 621-737, or consists of a larger, undefined portion, or consists of any smaller portion which may comprise one, two, or all three conserved domains disclosed in Table 2. Neither the specification nor the prior art teach whether all three of the conserved portions are "required" for catalytic activity in FAP α . Applicant states in the response filed 7/10/00 that the ellipses in Table 2 are provided to indicate amino acids not specifically shown between the amino acids specifically provided in the Table. One skilled in the art would therefore reasonably assume that the ellipses at the beginning and end of the amino acids provided also

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indicate amino acids not specifically shown. As the "beginning" and "end" portions are not specifically defined, and as the amino acids shown in Figure 2 are not specifically identified as solely those constituting the catalytic domain of FAP α , Table 2, alone, fails to fully and completely describe the catalytic domain of FAP α . The specification does not otherwise define or describe the catalytic domain of FAP α , nor does the specification specifically describe a fusion or chimeric protein consisting of the catalytic domain of FAP α and a portion of any other protein, therefore the specification fails to set forth a full and complete written description of the claimed subject matter.

For all of the reasons set forth above, claims 5 and 16-19 are rejected for lack of written description.

Conclusion

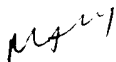
Claims 5 and 16-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications or (703) 872-9306 (RightFax).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.


Marjorie A. Moran
Examiner
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January 17, 2002


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